

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

I. Status of the Claims

Claims 1, 3 and 57 have been amended to delete the term “about.” Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1-57 will be pending with claims 11-12 and 18-55 withdrawn from consideration.

II. Rejection of Claims under 35 U.S.C. §103(a)

A. Ramirez and Self

Claims 1-10 and 56-57 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over U.S. Patent No. 5,632,996 to Ramirez et al. (“Ramirez”) in view of U.S. Patent No. 4,917,816 to Self (“Self”). Applicants respectfully traverse the rejection.

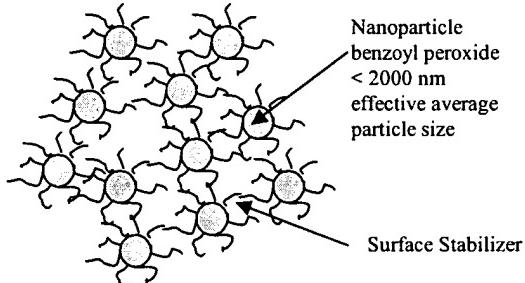
(i) **Alkylbenzoate of Ramirez’s composition does not read on the surface stabilizer of the claimed composition.**

The claimed invention is directed to a nanoparticulate composition comprising benzoyl peroxide particles having an effective average particle size of less than about 2000 nm and at least one surface stabilizer *associated with the surface* of the benzoyl peroxide particles.

Ramirez discloses compositions comprising benzoyl peroxide and a benzoic acid ester, such as an alkylbenzoate. The Examiner asserts that the alkylbenzoate of Ramirez’s composition reads on the surface stabilizer of the claimed invention. Applicants respectfully disagree.

Ramirez requires that benzoyl peroxide be “*solubilized*” in benzoic acid esters, such as an alkylbenzoate (see column 1, lines 61-67). In other words, alkylbenzoate is used as a solvent

rather than a surface stabilizer. In contrast, the claimed composition comprises benzoyl peroxide as solid particles, which is *not solubilized*. Instead, the surface stabilizer is *associated with the surface* of the benzoyl peroxide particles. The claimed composition is depicted in the diagram below:



(ii) The motivation to combine the references is lacking.

It is not surprising that Ramirez fails to disclose the particle size of benzoyl peroxide because benzoyl peroxide is *solubilized* in the alkylbenzoate or other benzoic acid esters in Ramirez's composition. The Examiner attempts to remedy this acknowledged deficiency of the primary reference by relying on Self's alleged teaching of the claimed particle size.

Ramirez describes a benzoyl peroxide composition by solubilizing benzoyl peroxide in a benzoic acid, such as an alkylbenzoate, thereby minimizing the water content in the composition to make an "anhydrous benzoyl peroxide paste composition." See column 3, lines 15-16 and 24-27. Ramirez further describes that C12-C15 alkyl benzoate replaces all the bound water of benzoyl peroxide (column 4, lines 3-6). In particular, Ramirez recommends against high water content in the benzoyl peroxide composition by stating that "a small amount of residual water (up to 3%) is functional," and that "[a]ny more than 5% water will precipitate the benzoyl peroxide" (column 4, lines 24-26). In view of Ramirez's teaching, one skilled in the art would have concluded that water is undesirable in the benzoyl peroxide composition.

The cited secondary reference, Self, on the contrary, relates to improving a benzoyl peroxide “dispersion in water” (see column 2, line 43, through column 3, line 10). The working examples of Self demonstrate that the water content of Self’s compositions is in the range between 20-40%, mostly around 30%, by a calculation of the total weight of all ingredients. As such, Ramirez and Self teach away from each other in terms of the water content of the benzoyl peroxide compositions. Therefore, the motivation to combine the teachings of these references is lacking.

(iii) The combined teachings of Ramirez and Self fail to render the claimed composition obvious.

As discussed supra, Ramirez fails to disclose the particle size of benzoyl peroxide in the composition because benzoyl peroxide is solubilized by a benzoic acid ester, such as an alkylbenzoate. Self discloses a particle size of less than 10 microns and that “a vast majority of same were from about 2 to about 5 microns in size” (column 7, lines 21-25).

The Examiner construes the claim language “about” as a plus or minus to the particle size of 2000 nm and thus takes a position that “‘about 2 microns’ obviously meets the limitations of about 1900 or about 2000 nm” (Office Action, page 5, lines 10-11). Nevertheless, the combined teachings of Ramirez and Self fail to render claims 3 and 57 obvious because Self does not describe a nanoparticulate benzoyl peroxide composition having an effective average particle size selected from the group consisting of less than 1900 nm, less than 1800 nm, less than 1700 nm, less than 1600 nm, less than 1500 nm, less than 1400 nm, less than 1300 nm, less than 1200 nm, less than 1100 nm, less than 1000 nm, less than 900 nm, less than 800 nm, less than 700 nm, less than 600 nm, less than 500 nm, less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 100 nm, less than 75 nm, and less than 50 nm.

Without acquiescing to the stated rationale of the rejection, Applicants choose to advance prosecution by amending the claims to delete the term “about.”

In view of the foregoing, Applicants respectfully request withdrawal of the rejection.

B. Ramirez, Self and Kanios

Claims 1-10, 14-16 and 56-57 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over Ramirez and Self and further in view of U.S. Patent no. 5,719,197 to Kanios et al. (“Kanios”). Applicants respectfully traverse the rejection.

Ramirez and Self are discussed in the foregoing paragraphs. Kanios is cited for the alleged teaching of bioadhesive compositions. Because Kanios fails to cure the deficiencies of Ramirez and Self as detailed above, the combined teachings of the cited art fail to render the claims obvious.

C. Ramirez, Self, Kanios and Bartnick

Claims 1-10, 13-17 and 56-57 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over Ramirez, Self and Kanios and further in view of U.S. Patent no. 5,399,353 to Bartnick et al. (“Bartnick”). Applicants respectfully traverse the rejection.

Similar to Kanios, Bartnick also fails to compensate for the stated deficiencies of Ramirez and Self. Moreover, it appears that the Examiner’s position is that PVP and lysozyme of Bartnick’s composition reads on the surface stabilizer of the claimed invention, as recited in claim 13. However, there is no reason for one skilled in the art to substitute PVP and lysozyme for the alkylbenzoate of Ramirez’s composition because there is no evidence that benzoyl peroxide can be solubilized in PVP or lysozyme.

Therefore, withdrawal of the rejections under 35 U.S.C. §103(a) is warranted.

III. Response to the Examiner's Request for Submission of Copending Applications

In the Office Action, the Examiner states that “Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action” (page 9, third paragraph).

No additional information is accompanying this response because Applicants have no other pending application related to nanoparticulate benzoyl peroxide compositions.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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